

SDS Hazard Communication Safety Data Sheet according to Regulation (EC) No. 1272/2008 [CLP]

IS Pac Spherasorb White to Violet

SDS Ref ISPac Spherasorb WV 12 September 2019

Issue 12th September 2019

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name/designation	IS Pac containing Spherasorb Soda Lime White to Violet Colour change
Product Code numbers	2183003
Substance name	Soda lime with indicator
Appearance	Clear plastic canister containing White solid granules and foam pads
Absorbent CAS No.	8006-28-8
REACH registration No.	Not applicable.

1.2 Relevant identified uses of the substance or mixture and uses advised against

For medical, veterinary or laboratory use to remove carbon dioxide from gas streams.

1.3 Details of the supplier of the safety data sheet

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2 Hazards identification of granules

EYE CONTACT: can cause serious and permanent eye injury.

SKIN CONTACT: causes burns that can be deep and poor in healing.

INGESTION: causes serious burns in the stomach and perforation.

INHALATION: causes burns in the lungs and respiratory tract that can be delayed. Can cause lung damage.

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazard classes and hazard categories	Hazard statements
Causes skin irritation.	H315
Causes serious eye damage.	H318

2.1.2 Classification according to Directive 67/548/EEC or 1999/45/EC

Hazard symbols	R Phrases
R41	Risk of serious damage to eyes
R 36/37/38	Irritating to eye, respiratory system and skin.

2.2 Label elements

2.2.1 Labeling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictogram(s)



Signal word: Warning

Class: Irritant

Hazard statements

Causes skin irritation.	H315
Causes serious eye damage.	H318

Precautionary statements

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302/P352	IF ON SKIN: Wash with plenty of soap and water.
P305/351/338.	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P332/313:	If skin irritation occurs: Get medical advice/attention
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2.2.2 Labeling (67/548/EEC or 1999/45/EC)

Hazard symbols



R phrases

R41	Risk of serious damage to eyes
R 36/37/38	Irritating to eye, respiratory system and skin.

S phrases

S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.
S2	Keep out of reach of children.
S26 S37/39	Wear suitable gloves and eye/face protection.
S45	In case of accident or if you feel unwell seek medical advice immediately and show label where possible.

2.3 Other hazards

None

2.4 Hazards identification of canister body and base/lids

Summary of most important information on hazards.

None

Specific danger/hazard

None

2.5 Hazards identification of foam pads

In case of a fire the product causes an intense heat and dense smoke. It is recommended that the smoke is not inhaled. Decomposition products may include soot, carbon monoxide, carbon dioxide, gaseous hydrocarbons and products containing nitrogen.

3. Composition/ Information on ingredients of granules

Ingredient	CAS No	EINECS/ELINCS	Content weight (%)
Calcium Hydroxide	1305-62-0	215-137-3	75 – 80 %
Sodium Hydroxide	1310-73-2	215-185-5	Under 2 %
Zeolite	1318-02-1	215-283-8	4 – 5 %
Ethyl Violet	2390-59-2	219-231-5	Under 0.1 %
Water			13.5 – 17.5 %

Classification according to Regulation (EC) No. 1272/2008 [CLP]

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

3.1 Composition/ Information on ingredients of canister body and lid/base

	Ingredient	CAS No
Canister body and base/lids	Styrene Homopolymer	9003-53-6
Foam pads		

3.2 Composition/ Information on ingredients of foam pads

	Ingredient	CAS No
Foam pads	Polyurethane Polymer	9010-69-9

4. First-aid measures

4.1 General information

IF exposed: Immediately call a POISON CENTER or doctor/ physician. If unconscious place in recovery position and seek medical advice. Never give anything by mouth to an unconscious person or a person with cramps. Change contaminated clothing. Do not leave affected person unattended.

4.2 After inhalation

Immediately call a POISON CENTER or doctor/ physician. Remove casualty to fresh air and keep warm and at rest. If breathing is irregular or stopped, administer artificial respiration.

4.3 In case of skin contact

After contact with skin, wash immediately with plenty of water and soap. Remove contaminated clothing immediately. Immediate medical treatment is required because corrosive injuries that are not treated are hard to cure.

4.4 After eye contact

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Do NOT allow victim to rub or keep eyes closed. Consult an ophthalmologist. Protect uninjured eye. Remove contact lenses, if present and easy to do. Continue rinsing.

4.5 After ingestion

Immediately call a POISON CENTER or doctor/ physician. Do not induce vomiting. Rinse mouth thoroughly with water. Give nothing to eat or drink.

4.6 Self-protection of the first aider

Avoid inhalation and skin contact. Do not get into eyes and do not ingest. Wear protective gloves and goggles.

4.7 Information to physician:

Symptoms No data available

Hazards No data available

Treatment No data available

5. Firefighting measures

5.1 Suitable extinguishing media

The product itself does not burn and is not considered to be a fire hazard.

The product is not considered to be an explosive hazard.

Packaging may be combustible.

Co-ordinate fire-fighting measures to the fire surroundings.

5.2 Extinguishing media which must not be used for safety reasons:

USE POWDER if possible.

Avoid water if possible. If water is the only extinguishing media available, do not get water inside containers. This may result in alkaline run off water.

DO NOT USE CARBON DIOXIDE

5.3 Special hazards arising from the substance or mixture

Extreme exothermic reactions with pure / high concentrations of carbon dioxide.

Reacts aggressively with acids.

5.4 Advice for firefighters

Keep away from acids and pure / high concentrations of carbon dioxide.

5.5 Additional information

Do not allow any run-off from fire-fighting to enter drains or water courses.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protection equipment. Avoid generation of dust. Do not breathe dust. Provide adequate ventilation. Remove persons to safety.

6.2 Environmental precautions

Do not allow product to enter into surface water or drains.

6.3 Methods and material for containment and cleaning up

Avoid contact with skin or inhalation of spillage, dust or vapour. Wear necessary protective equipment. Small amounts can be picked up using moist disposable cloth. Shovel into suitable dry containers for disposal and cover. Flush the area with water. Avoid dust formation.

6.4 Additional information

No data available

7. Handling and storage

7.1 Precautions for safe handling

Do not handle broken packages without protective equipment.

Avoid spilling,

Wash thoroughly after handling.

Use with adequate ventilation and dust extractor if necessary. Minimize dust generation and accumulation.

Do not get in eyes, on skin, or on clothing. Do not ingest or inhale.

7.2 Conditions for safe storage, including any incompatibilities

Store in a tightly closed/sealed container.

Store in a cool, dry, well-ventilated area away from incompatible substances.

Do not store in direct sunlight.
Keep away from strong acids.
Store protected from moisture.

Store at temperatures ranging from -20°C to $+50^{\circ}\text{C}$.

Do not allow to desiccate (dry out).

Facilities storing or utilizing this material should be equipped with an eyewash facility.

Store in a safe place away from children and not together with or near food, animal feed.

7.3 Specific end use(s)

No data available

8. Exposure controls / Personal protection.

8.1 Appropriate engineering controls

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

8.2 Personal protective equipment



8.2.1 Eye / face protection

Use approved safety goggles or face shield.

8.2.2 Skin protection

Use protective gloves made of: Rubber or plastic.

8.2.3 Protective clothing

Wear appropriate clothing to prevent reasonably probable skin contact

8.2.4 Respiratory protection

Work in fume cupboard if possible

Wear respirator if there is dust formation. Dust filter P2 (for fine dust).

8.4 Additional information

Wash hands before breaks and after work. Avoid contact with skin and eyes. When using do not eat, drink or smoke. have eye shower equipment available.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties of granules

(a) Appearance

Physical state Solid porous granules 3- 4 mm.

Colour No White

(b) Odour Slight chemical smell

(c) Odour threshold No data available

Safety relevant basic data

- pH pH14
- Melting point/freezing point Not applicable.
- Initial boiling point and boiling range Not applicable.
- Flash point No data available
- Evaporation rate Not applicable
- Flammability Not applicable
- The product is not considered to be an explosive hazard.
- Vapour pressure No data available
- Vapour density No data available
- Solubility Slightly soluble in water.
Aqueous solutions are alkaline.
- Auto-ignition temperature No data available
- Decomposition temperature Thermal decomposition to oxides at over 500 deg C
- Viscosity Not applicable
- Explosive properties Not applicable.
The product is not considered to be an explosive hazard.
- Oxidising properties Not applicable

9.2 Other information

Bulk density 0.85 g/ml +/- 0.02.

9.1 Information on basic physical and chemical properties of canister body and lid/base

Physical properties :

Appearance : Clear moulded plastic canister body and base/lid

Color : Colorless

Odor : Faint

pH : none

Phase change temperature :

Melting point : This Product gradually becomes soft over a broad range . (between 100-150 degree)

Flash point : > 350 deg C

Ignition temperature : about 490 deg C

Explosion : not available

Explosion limit Upper : not available.

Explosion limit Lower : 60g/m³(particle size<0.2mm)

Density : 620kg/m³

Solubility : not available

Solubility in solvent : not available

Insoluble in water.

9.2 Information on basic physical and chemical properties of foam pads

Appearance: solid foam.

Colour: cream (or other if coloured)

facings in different types/colours are possible

Smell: none

Core density: 30 to 40 kg/m³ (at 20°C and depending on the thickness)

Auto ignition temperature: Group 1 : > 300°C

Group 2 : > 500 °C

Risk of explosion: not applicable.

10. Stability and reactivity

10.1 Reactivity

Extreme exothermic reactions with pure / high concentrations of carbon dioxide.

Reacts aggressively with acids.

Variable reactivity with different acidic gases.

10.2 Chemical stability

Chemically stable unless in contact with other substances.

10.3 Possibility of hazardous reactions

Extreme exothermic reactions with pure / high concentrations of carbon dioxide.

Reacts aggressively with acids. Potentially toxic fumes can be produced with some acids.

10.4 Conditions to avoid

Avoid contact with acids.

Do not use with trichloroethylene and chloroform.

Avoid contact with pure / high concentration of Carbon Dioxide.

10.5 Incompatible materials.

The product will corrode most metal and degrade condensation polymers.

10.6 Hazardous decomposition products

Fire or high temperatures create can create harmful fumes of sodium oxide and calcium oxide.

Low level of Amines may be released from decomposition of Ethyl Violet.

10.7 Additional information

No data available

10.8 Information on Stability and reactivity of canisters and body/lids

Stability and Reactivity

Stability :

This product is considered a stable material under normal and anticipated storage and handling conditions.

Reactivity :

It has no self-reactivity at the room temperature. Decomposes and generates gases at high temperature.

Decomposition products :

Trace quantities, styrene monomer, aldehydes and organic acids may be formed.

Incompatible materials: Strong oxidizing agents.

10.9 Information on Stability and reactivity of foam pads

The product is stable in normal application conditions.

Conditions that must be avoided: long term contact or proximity of a heat source.

Materials that must be avoided: None in case the product is handled according to technical documentation of the product.

Dangerous decomposition products: None in normal application conditions

In case of a fire the product causes an intense heat and dense smoke. It is recommended that the smoke is not inhaled. Decomposition products may include soot, carbon monoxide, carbon dioxide, gaseous hydrocarbons and products containing nitrogen.

11 Toxicity Information.

No toxicity data is available for finished mixture.

Health warnings

This chemical may cause skin/eye irritation and burns (corrosive). SYMPTOMS

AFTER INHALATION. Coughing. Smarting in nose, throat and mouth. Severe smarting. Tearing eyes. Swollen eye lids. Corneal damage. SYMPTOMS AFTER INGESTION. Smarting in mouth and throat. Stomach pain. Diarrhoea.

Route of entry

Inhalation. Skin absorption. Ingestion.

Target organs

Eyes. Gastrointestinal tract. Respiratory system, lungs. Skin. Mucous membranes.

11.2 Available toxicity information of major component Calcium Hydroxide.

Toxicity endpoints Outcome of the effects assessment

Acute toxicity Calcium Hydroxide is not acutely toxic.

Oral LD50 > 2000 mg/kg bw (OECD 425, rat)

Dermal LD50 > 2500 mg/kg bw (OECD 402, rabbit)

Inhalation no data available

Classification for acute toxicity is not warranted.

Skin irritation/corrosion

A risk of serious damage to the eye

(eye irritation studies (*in vivo*, rabbit). Based on experimental results, calcium hydroxide requires classification as severely irritating to the eye (H318 -Causes serious eye damage). Skin irritation: Calcium hydroxide is irritating to skin (*in vivo*, rabbit). Based on experimental results, calcium hydroxide requires classification as irritating to skin (H315 – Causes skin irritation).

Respiratory or skin sensitization

No data available. Calcium hydroxide is considered not to be a skin sensitiser, based on the nature of the effect (pH shift) and the essential requirement of calcium for human nutrition. Classification for sensitization is not warranted.

Germ cell Mutagenicity

Bacterial reverse mutation assay (Ames test, OECD 471): Negative

Mammalian chromosome aberration test: Negative

In view of the omnipresence and essentiality of Ca and of the physiological non-relevance of any pH shift induced by lime in aqueous media, lime is obviously void of any genotoxic potential including germ cell mutagenicity. Classification for genotoxicity is not warranted.

Carcinogenicity

Calcium (administered as Ca-lactate) is not carcinogenic (experimental result, rat).

The pH effect of calcium hydroxide does not give rise to a carcinogenic risk.

Human epidemiological data support lack of any carcinogenic potential of

calcium hydroxide.

Classification for carcinogenicity is not warranted.

Toxicity for reproduction

Calcium (administered as Ca-carbonate) is not toxic to reproduction (experimental result, mouse).

The pH effect does not give rise to a reproductive risk.

Human epidemiological data support lack of any potential for reproductive toxicity of calcium hydroxide.

Both in animal studies and human clinical studies on various calcium salts no reproductive or developmental effects were detected. Also see the Scientific Committee on Food (Section 16.6). Thus, calcium hydroxide is not toxic for reproduction and/or development.

Classification for reproductive toxicity according to regulation (EC) 1272/2008 is not required

STOT – single exposure

From human data it is concluded that Ca(OH)₂ is irritating to the respiratory tract.

As summarized and evaluated in the SCOEL recommendation (Anonymous, 2008), based on human data calcium hydroxide is classified as irritating to the respiratory system (H335

– May cause respiratory irritation)].

11.3 Information on Toxicity Information of canisters and body/lids

Acute toxicity :

Include 50% Lethal Dose. Oral LD₅₀ > 2000 mg/kg

Effects on skin, eyes and others : Low acute toxicity.

Allergenic and/or sensitizing effects : Not known.

Chronic and/or long term toxicity :

No data

Carcinogenic effects :

No data

Mutagenic effects :

No data

Teratogenic effects :

No data

Toxicity for reproduction :

No data

Others : None

11.4 Information on Toxicity Information of foam pads

Inhalation: no known toxic risk.

Ingestion: no known toxic risk.

Contact with the skin: no known toxic risk.
Contact with the eyes: no known toxic risk.

12. Ecological information

12.1 Ecotoxicity

Acute (short-term) fish toxicity

LC50: No data available

EC50

species:

Exposure time

Chronic (long-term) fish toxicity

LC50: No data available

EC50

species:

Exposure time

Acute (short-term) daphnia toxicity

LC50: No data available

EC50

species:

Exposure time

Chronic (long-term) daphnia toxicity

LC50: No data available

EC50

species:

Exposure time

Acute (short-term) algae toxicity

LC50: No data available

EC50

species:

Exposure time

Chronic (long-term) algae toxicity

LC50: No data available

EC50

species:

Exposure time

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT assessment

No data available

12.6 Other adverse effects

No data available

Summary:

Ecotoxicity Not regarded as dangerous for the environment.

Bioaccumulative potential No bioaccumulation expected.

Acute fish toxicity Can cause acute death of fish and aquatic organisms.

12.7 Ecological information on canister and body/lids

Bioaccumulation :

N.A.

Fish toxicity :

N.A.

Others :

Don't dump into all of the sea and the water area so that birds and marine creatures will not eat it.

12.8 Ecological information on foam pads

Maneuverability of the product: The product floats, given the fact that its density is lower than that of water.

Degradability: The product is not biologically degradable and is insoluble (it does not disintegrate in contact with water).

Bioaccumulation potential: The product is not toxic and is stable. There is no release of organic substances.

13. Disposal considerations

The following information is a guideline only. Disposal of the waste IS Pac containing Spherasorb must be in accordance with local authority regulations, following a risk analysis by the user.

The IS Pac containing Spherasorb does not contain any toxic materials and is not classified as a hazardous material.

The composition of the waste IS Pac containing Spherasorb will depend upon the conditions of use, however, it will contain:

- Calcium Carbonate (varying major proportion)
- Calcium Hydroxide (varying sometimes major proportion)
- Sodium Carbonate (varying minor proportion)
- Sodium Hydroxide (varying minor proportion)
- Zeolite (minor proportion)
- Water (varying major proportion)
- There will also be a trace of indicator dye.
- There may be residual traces of volatile anaesthetics.
- In the case of infectious patients, consideration should be given in line with handling of infectious clinical waste.

Waste class of the IS Pac containing Spherasorb that has not been clinically used.

Spherasorb, falls within the category of a Sodium Hydroxide/Calcium Hydroxide soda lime and so may still contain slightly above 1 %, H314 waste (in this case sodium hydroxide). and above 10 % H315, H318 waste (in this case calcium hydroxide). untreated waste soda lime's have the waste property HP4 irritant and corrosive, even though they may sometimes fall below the scope for this classification.

Therefore, Spherasorb that has not been clinically used, would require the European Waste Catalogue number 18 01 06* ('Chemical consisting of or containing hazardous substances'), the same as standard soda lime's.

Waste class of the IS Pac containing Spherasorb that has been clinically used within anaesthesia systems

After clinical use of the IS Pac containing Spherasorb during anaesthesia, as with any soda lime, consideration should be given to the consequence of its clinical use, especially with an infectious patient (which will not always be known).

Whilst breathing filters are in use to limit potential cross contamination between patients and anaesthetic breathing systems, the instructions for use of anaesthetic machines sometimes advise that re-usable absorbers, if used with infectious patients, should be autoclaved per patient, even when filters are used at the Y piece or on the machine inspiratory and expiratory ports. Furthermore, used soda lime, even when remaining significantly alkaline, cannot be guaranteed to present an antibacterial environment.

Disposal.

Considering the above, Intersurgical advise that following clinical use of the IS Pac containing Spherasorb during anaesthesia, the user conducts a risk assessment to assess whether the it also required the further classification under the European Waste Catalogue number 18 01 04 ('wastes whose collection and disposal is not subject to special requirements in order to prevent infection'), but also with the potential for 18 01 03* (waste whose collection and disposal is subject to special requirements in order to prevent infection).

Following this, that clinically used IS Pac containing Spherasorb is treated at source with minimal handling; this being treated at source by incineration within a mixture of other clinical waste. In this way, any H314 and H318 substances will be further dispersed within the other ash material.

14. Transport Information

Not regulated: There are no restriction for transport by, road, rail or air.

14.1 United nations number (ADR) Exempt under special provision 62

14.2 Proper shipping name (ADR) Exempt under special provision 62

14.3 Transport class/s (ADR) Exempt under special provision 62

14.4 Packing group (ADR) Exempt under special provision 62

- 14.5 Hazard No (ADR): 80: Exempt under special provision 62
 14.6 Environmental hazards (ADR) Exempt under special provision 62
 14.7 Special procedures (ADR) Exempt under special provision 62.

14.8 This substance contains less than 4 % sodium hydroxide and is not subject to the requirements of ADR under special provision 62

14.9 This substance contains less than 4 % sodium hydroxide and is not subject to IATA under special provision A16:

15. Regulatory Information.

15.1 Safety, health and environmental regulations.
 The product is classified in accordance with EC regulation 1272/2008 (CLP). Other regulatory information is not applicable to this product.

15.2 Chemical Safety Assessment: Not applicable

16. Other information

This safety data sheet has been revised in accordance to EC regulation 1272/2008 (CLP), by Intersurgical, to the best of its knowledge.

16.1 Source of data:

Guidance on Labeling and Packaging under the CLP regulation 2011
 CLP-an introduction to the new regulations, REACH READY 15/2/2011
 Globally Harmonized System of Classification, Chapter 2
 European Waste Catalogue (2001/118/EC as amended), Safety data sheets of ras materials and packaging. Other supplier safety data sheets.

16.2 Hazards identification

Hazard statements and Precautionary statements are given in section 2.

EYE CONTACT: can cause serious and permanent eye injury.

SKIN CONTACT: causes burns, that can be deep and poor in healing.

INGESTION: causes serious burns in the stomach and perforation.

INHALATION: causes burns in the lungs and respiratory tract, that can be delayed. Can cause lung damage.

Classification according to Directive 67/548/EEC or 1999/45/EC

Hazard classes and hazard categories	Hazard statements
Causes skin irritation.	H315
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Labeling according to Regulation (EC) No. 1272/2008 [CLP]



Signal word: Warning

Class: Irritant

Precautionary statements

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302/P352	IF ON SKIN: Wash with plenty of soap and water.
P305/351/338.	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332/313:	If skin irritation occurs: Get medical advice/attention

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